

United States Patent and Trademark Office

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Vignia 22313-1450 www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-----------------|----------------------|---------------------------------|------------------|
| 10/053,620 | 01/24/2002 | Kyu Yong Jung | 05823.0199.01000 | 9253 |
| 75 | 90 . 06/30/2003 | | | |
| Finnegan, Henderson, Farabow, Garrett & Dunner, L.L.P. 1300 I Street, N.W. | | | EXAMINER | |
| | | | COE, SUSAN D | |
| Washington, DC 20005-3315 | | | ART UNIT | PAPER NUMBER |
| | | | 1654 DATE MAILED: 06/30/2003 | 5 |

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | Application No. | Applicant(s) | | | |
|---|---|-------------------------|--|--|--|--|
| | | 10/053,620 | JUNG ET AL. | | | |
| | Office Action Summary | Examiner | Art Unit | | | |
| | | Susan Coe | 1654 | | | |
| | The MAILING DATE of this communication appears on the cover she t with the correspondence address Period for Reply | | | | | |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status | | | | | | |
| 1) | <u> </u> | | | | | |
| 2a)□ | • | s action is non-final. | | | | |
| 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213. | | | | | | |
| Disposition of Claims | | | | | | |
| •— | Claim(s) 1-4 and 6-13 is/are pending in the application. | | | | | |
| | 4a) Of the above claim(s) is/are withdrawn from consideration. | | | | | |
| 5) Claim(s) is/are allowed. | | | | | | |
| 7) | 6)⊠ Claim(s) <u>1-4 and 6-13</u> is/are rejected. 7)□ Claim(s) is/are objected to. | | | | | |
| , | Claim(s) are subject to restriction and/or | r election requirement. | | | | |
| Application Papers | | | | | | |
| 9)□ | The specification is objected to by the Examine | г. | | | | |
| 10)☐ The drawing(s) filed on is/are: a)☐ accepted or b)☐ objected to by the Examiner. | | | | | | |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). | | | | | | |
| 11) ☐ The proposed drawing correction filed on is: a) ☐ approved b) ☐ disapproved by the Examiner. | | | | | | |
| If approved, corrected drawings are required in reply to this Office action. | | | | | | |
| 12)☐ The oath or declaration is objected to by the Examiner. | | | | | | |
| Priority under 35 U.S.C. §§ 119 and 120 | | | | | | |
| 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). | | | | | | |
| a) | ☑ All b)☐ Some * c)☐ None of: | | | | | |
| | 1. Certified copies of the priority documents have been received. | | | | | |
| | 2. Certified copies of the priority documents have been received in Application No. <u>09/850,269</u> . | | | | | |
| 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. | | | | | | |
| 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application). | | | | | | |
| a) ☐ The translation of the foreign language provisional application has been received. 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121. | | | | | | |
| Attachment(s) | | | | | | |
| 2) Notic | ce of References Cited (PTO-892) ce of Draftsperson's Patent Drawing Review (PTO-948) mation Disclosure Statement(s) (PTO-1449) Paper No(s) 1 | 5) Notice of Informal | y (PTO-413) Paper No(s) Patent Application (PTO-152) | | | |

Art Unit: 1654

DETAILED ACTION

- 1. The preliminary amendment filed October 7, 2002 has been received and entered.
- 2. Claim 5 has been cancelled.
- 3. Claims 10-13 have been added.
- 4. Claims 1-4 and 6-13 are currently pending and are examined on the merits.

Priority

Applicant's claim for priority as a continuation-in-part of US Pat. Appl. No. 09/850,269 is acknowledged.

Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). The certified copy has been filed in parent Application No. 09/850,269, filed on May 8, 2001.

Claim Objections

Claims 7 and 9 are objected to because of the following informalities: in line 4 of the claims, "parenteral" is misspelled as "parenternal." Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Art Unit: 1654

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 1-4 and 6-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Pat. No. 6,010,702 in view of Japanese Pat. Appl. No. 07025777 A, Japanese Pat. Appl. No. 07179342 A, Derwent English abstract of Chinese Pat. Appl. No. 1207942 A, the Internet description of GERIFORTE tablets ((<<www.eisra.nl/gb/complex/geriforte.htm>>) (1998)), US Pat. No. 5,707,631, and Japanese Pat. Appl. No. 06056684 A.

Applicant's claim 1 is drawn to a composition that comprises Polygoni multiflori Radix and at least three ingredients selected from Poria, Aurantii nobilis Pericarpium, Glycyrrhizae Radix, Pinelliae Tuber, and Zingibreis Rhizoma. Claim 2 adds at least one ingredient selected from Polygalae Radix, Caryophylli Flos, Arisaematis Rhizoma, Gastrodiae Rhizoma, Acori Graminei Rhizoma, Ostericum Koreanum or Curcuma Longae Rhizoma, Caulis Phyllostachyos or Folium Phyllostachyos, Bombycis Batryticatus, Fructus immaturs ponciri, Cyperi Rhizoma, and Saussurea Radix. Applicant also has specifically defined two compositions in claims 3 and 4. The specific composition in claim 3 is Polygoni multiflori Radix, Gastrodiae Rhizoma, Acori Graminei Rhizoma, Ostericum Koreanum or Curcuma Longae Rhizoma, Caulis Phyllostachyos or Folium Phyllostachyos, Bombycis Batryticatus, Fructus immaturs ponciri, Poria, Aurantii



Art Unit: 1654

nobilis Pericarpium, Glycyrrhizae Radix, and Zingibreis Rhizoma. The specific composition of claim 4 is Polygoni multiflori Radix, Polygalae Radix, Caryophylli Flos, Zingibreis Rhizoma, Arisaematis Rhizoma, Gastrodiae Rhizoma, Acori Graminei Rhizoma, Curcuma Longae Rhizoma, Folium Phyllostachyos, Bombycis Batryticatus, Fructus immaturs ponciri, Poria, Aurantii nobilis Pericarpium, Glycyrrhizae Radix, and Pinelliae Tuber.

US '702 teaches a composition comprising 6 to 24 weight parts of Arisaematis rhizome, 5 to 15 weight parts of Gastrodiae rhizome, 5 to 15 weight parts of Acorus Graminecus, 5 to 15 weight parts of Ostericum Koreanum, 5 to 15 weight parts of Bambusae Caulis In Taenium, 5 to 15 weight parts of Bombycis Corpus, 5 to 15 weight parts of Ponciri Fructus, 5 to 15 weight parts of Hoelen, 5 to 15 weight parts of Pinelliae tuber, 3 to 9 weight parts of Aurantii nobilis pericarpium, and 3 to 9 weight parts of Glycyrrhizae radix. From applicant's current specification, page 7, and the specification of the priority document (US Appl. No. 09/850,269), page 5, the plant names have been defined such that Acorus Graminecus is the same as Acori Graminei, Bambusea Caulis In Taenium is the same as Phyllostachyos, Bombycis Corpus is the same as Bombycis Batryticatus, Ponciri Fructus is the same as Fructus immaturus ponciri, and Hoelen is the same as Poria.

The composition of US '702 is extracted with water or ethanol (see claims 1 and 2). The composition is used to treat dementia (see column 2, lines 1-6). US '702 teaches formulating their composition as pellets, extract liquid preparations, powders, granules, percolated preparations (synonymous with infused preparation), boiled preparations (synonymous with decocted preparation), tablets, capsules, or injectable preparations (synonymous with parenteral

Art Unit: 1654

preparations) (see column 2, lines 27-31). US '702 does not teach using Zingiber, Polygalae, Polygoni multiflori, Caryophylli, Saussurea, or Cyperi in the composition.

JP '777 teaches using Zingiber rhizome extracts to treat dementia (see English abstract).

JP '342 teaches using Polygalae radix extracts to treat dementia (see English abstract).

CN '942 teaches using Polygoni multiflori to treat dementia. The reference uses the entire plant which would include the radix.

GERIFORTE website teaches using Eugenia caryophyllata and Curcuma longa to treat dementia. The reference uses the entire plant which would include the flos and the rhizome. From applicant's specification, page 7, Eugenia caryophyllata is the same as Caryophylli.

US '631 teaches using Saussurea radix to treat Alzhemier's disease (see column 2, lines 4 and 42). Alzheimer's disease is well known to cause dementia.

JP '684 teaches using Cyperus rotundus to treat dementia (see English abstract). The reference uses the entire plant which would include the rhizome. From applicant's specification, page 7, Cyperus rotundus is the same as Cyperi.

The references show that it was known in the art at the time of the invention to use the claimed ingredients in compositions that treat dementia. It is well known that it is prima facie obvious to combine two or more ingredients each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is useful for the same purpose. The idea for combining them flows logically from their having been used individually in the prior art. In re Pinten, 459 F.2d 1053, 173 USPQ 801 (CCPA 1972); In re Susi, 58 CCPA 1074, 1079-80; 440 F.2d 442, 445; 169 USPQ 423, 426 (1971); In re Crockett, 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960).

Art Unit: 1654

Based on the disclosure by JP '777, JP '342, CN '942, GERIFORTE website, US '631, and JP '684 that Zingiber, Polygalae, Polygoni multiflori, Caryophylli, Curcuma longa, Saussurea, and Cyperi are used in compositions to treat dementia, an artisan of ordinary skill would have a reasonable expectation that adding these ingredients to the composition taught by US '702 would also be useful in creating a composition to treat dementia. Therefore, the artisan would have been motivated to combine Zingiber, Polygalae, Polygoni multiflori, Caryophylli, Curcuma longa, Saussurea, or Cyperi with the composition of Arisaematis, Gastrodiae, Acorus Graminecus, Ostericum Koreanum, Bambusae Caulis In Taenium, Bombycis Corpus, Ponciri, Hoelen, Pinelliae, Aurantii nobilis, and Glycyrrhizae taught by US '702. No patentable invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients. See In re Sussman, 1943 C.D. 518; In re Huellmantel 139 USPQ 496; In re Crockett 126 USPQ 186.

The combined references do not specifically teach adding the ingredients in all of the amounts claimed by applicant. However, US '702 teaches that the ingredient amounts used in a composition to treat dementia can vary over a wide range of relative percentages (see claim 1). Therefore, the reference shows it was known in the art that herbal ingredients in a composition to treat dementia can be varied in order to formulate the composition in a manner that best achieves the desire result of treating dementia. Thus, based on the teaching of US '702 of varying the ingredient amount, a person of ordinary skill in the art would be motivated to formulate the composition taught by the combination of US '702, JP '777, JP '342, CN '942, GERIFORTE website, US '631, and JP '684 in the amounts claimed by applicant.

Application/Control Number: 10/053,620 Page 7

Art Unit: 1654

6. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Coe whose telephone number is (703) 306-5823. The examiner can normally be reached on Monday to Thursday from 8:00 to 5:30 and on alternating Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can be reached on (703) 306-3220. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Susan Coe, Examiner

June 27, 2003